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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,516	02/06/2002	Gillian Rosemary Bullock	4-30755B	4159

1095 7590 11/02/2005

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,516	BULLOCK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,11,12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/468,663.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2005 has been entered.

Action Summary

The rejection of claims 7-12 and 17-23 under 35 U.S.C. 102(a) as being anticipated by Wagner et al. (WO 97/49394) is hereby expressly withdrawn in view of Applicant's amendment and cancellation of the claims.

The rejection of claims 13 and 24 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) in view of Pool et al.(1998) is hereby expressly withdrawn in view of Applicant's cancellation of the claims 7 and 17-23.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) of record.

Wagner et al. teach a solid oral dosage forms comprising an active agent valsartan and **optionally** HCTZ. (abstract). Wagner et al. teach that valsartan is preferably in its free form, that is, not in one of its salt forms. (page 4, line 11). Wagner et al. teach crospovidine is most preferred disintegrants in the dosage form and the dosage range of crospovidone is preferably present in an amounts of from 10 to 20 %, e.g. about 13% by weight. (page 4, lines 22-23, and page 7, lines 20-23, page 15 Example 2). Wagner et al. teach preferred dosage range of valsartan as 10 to 250mg consists entirely of valsartan and the effective amounts can be easily determined by person skilled in the art by routine experimentation and with no undue burden. (page 2, lines 15-22). Wagner et al. teach the binder can be employed as an additive and microcyrstallin cellulose is preferred in the dosage form. (page 5, first and last

paragraph; page 7, 3rd paragraph, last sentence). Wagner et al. teach the amount of binder may vary within a range of from about 10 to 45% by weight. (page 5, last paragraph, 4th sentence).

Wagner does not expressly illustrate an example of the dosage form comprising **more than 30%** of microcrystalline cellulose.

It would have been obvious to one of ordinary skill in the art to modify the illustrated example of Wagner and employ more than 30% of microcrystalline cellulose because Wagner teach that binder such as microcrystalline cellulose can be employed from about 10 to 45%. One would have been motivated to make such a modification in order to successfully formulate valsartan solid dosage form within the general range of binder (microcrystalline cellulose) anywhere between 10 to 45% taught by Wagner.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed June 17, 2005 have been fully considered but they are not persuasive. Applicants argue that Wagner does not explicitly teach a valsartan composition comprising **more than 30%** microcrystalline cellulose. However, this is not persuasive because as also pointed out by the Applicants' that the binders including

microcrystalline cellulose as being from 10 to 45% is well taught by Wagner which encompasses Applicants' amount of microcrystalline cellulose present more than 30%. Applicants further argue that as originally filled, on page 24, lines 13-15, after exhaustive testing, applicants determined that increasing the amount of microcrystalline cellulose to greater than 30%, improves the bioavailability of solid formulation. However, this is not persuasive because there is no comparative data to support to determine such improvement. Therefore, one of ordinary skill in the art would formulate valsartan composition comprising microcrystalline cellulose as being from 10 to 45% which includes Applicants amount as being above 30% up to 45% as taught by Wagner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
October 24, 2005